

FEB 28 2000

K000409

SPECIAL 510(k) Notification  
T-REX™ Biopsy Forceps

## Section 4 Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

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|---------------------------|-------------------------------------|--|
| <b>General Provisions</b> | <b>Submitter's Name and Address</b> | Boston Scientific Corporation<br>Northwest Technology Center,<br>Inc.<br>17425 N.E. Union Hill Road<br>Redmond, WA 98052 |
|                           | <b>Contact Person</b>               | Jocelyn Kersten<br>425-556-1667<br>425-558-1400 (fax)  |
|                           | <b>Classification Name</b>          | Device, biopsy, endomyocardial<br>(74DWZ)  |
|                           | <b>Common or Usual Name</b>         | Endomyocardial Biopsy Forceps  |
|                           | <b>Proprietary Name</b>             | T-REX Biopsy Forceps   |

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|--------------------------------------|---|--|
| <b>Name of Predicate<br/>Devices</b> | <u>Predicate Device</u><br>T-REX Biopsy Forceps | <u>510(k) Reference No.</u><br>K973818 |
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| <b>Device Description</b>                       | The T•REX™ biopsy forceps are designed to allow percutaneous access to the right or left ventricles of the heart in order to obtain diagnostic tissue samples. The forceps consist of three main components: a handle ergonomically designed for comfortable use, a shaft and surgical stainless steel cutting jaws. |
| <b>Intended Use</b>                             | The T•REX™ biopsy forceps are intended to obtain endomyocardial biopsy specimens. The specimens are taken for diagnosis of diseased heart tissue or for identification and monitoring of rejection factors in a transplanted heart.  |
| <b>Summary of Technological Characteristics</b> | The proposed T-REX biopsy forceps is similar in construction and materials to the currently marketed T-REX biopsy forceps.   |
| <b>Test Summary</b>                             | The proposed T-REX biopsy forceps is considered to be substantially equivalent to the currently marketed T-REX biopsy forceps based on a comparison of the intended uses and designs and results of the testing and evaluations performed.   |

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 28 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Jocelyn Kersten  
Senior Regulatory Affairs Specialist  
Boston Scientific Corporation  
Northwest Technology Center, Inc.  
17425 N.E. Union Hill Road  
Redmond, WA 98052

Re: K000409  
T-REX™ Biopsy Forceps  
Regulatory Class: II (two)  
Product Code: DWZ  
Dated: February 4, 2000  
Received: February 8, 2000

Dear Ms. Kersten:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

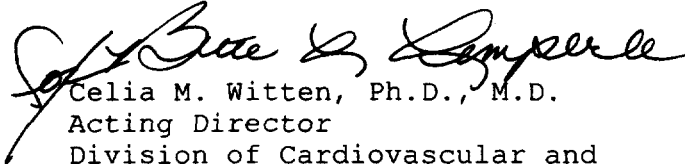
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for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name and title.

Celia M. Witten, Ph.D., M.D.  
Acting Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Section 3 Indication for Use**

K 000 409

**510(k) Number**

**Device Name**

T-REX™ Biopsy Forceps

**Indications for Use**

The T-REX biopsy forceps is used to obtain endomyocardial biopsy specimens from the right or left ventricle via percutaneous arterial or venous approach.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over The Counter Use \_\_\_\_\_

*Sean R. Gember*  
(Division Sign-Off) (Optional Format 1-2-96)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K 000 409

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